

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The March 1, 2006, telephonic interview between Examiners Dixon and Ragonese and applicant's undersigned attorney is acknowledged. The substance of that interview is summarized as follows. On March 1, 2006, Examiners Dixon and Ragonese called applicant's undersigned attorney to discuss the proposed amendment to claim 15 that the undersigned had previously sent to Examiner Dixon in response to her February 22, 2006, telephone call where she had indicated that all pending claims of the application were allowable except claim 15 which lacked a point of origin for the limitation "in a substantially radial direction." While stating that the proposed amendment to claim 15 would render the claim allowable, Examiners Dixon and Ragonese indicated that the previous amendment filed by the prior firm was non-compliant because the text for canceled claim 32 was not removed. Examiners Dixon and Ragonese then informed the undersigned that the proposed amendment to claim 15 would need to be submitted in a supplementary amendment, in which non-compliant claim 32 is corrected and all withdrawn claims are canceled. In addition, Examiners Dixon and Ragonese mentioned that there were double patenting issues over U.S. Patent Nos. 6,845,772 and 6,347,629, which could be overcome by the filing of terminal disclaimers. In view of the additional double patenting issues that were brought up, the applicant's undersigned attorney, instead of agreeing to submit a supplementary amendment and terminal disclaimers, requested Examiners Dixon and Ragonese to mail out a written office action. In response, Examiners Dixon and Ragonese advised the undersigned to still submit a supplementary amendment to correct non-compliant claim 32 by 5:00 PM E.S.T. on March 2, 2006. Accordingly, on March 2, 2006, the undersigned filed a supplementary amendment only correcting non-compliant claim 32 (without including any other amendments).

The rejection of claims 16, 17, and 22 under 35 U.S.C. § 112 is respectfully traversed in view of the above amendments and the following remarks.

It is the position of the U.S. Patent and Trademark Office ("PTO") that claims 16, 17, and 22 are indefinite because they recite the term "magazine" that holds the medicament, while the parent claim, i.e., claim 15, recites the term "spool". In addition, the

PTO asserts that the terms “spool” and “magazine” are essentially functional equivalents and that there is insufficient antecedent basis for the limitation “magazine” in claims 16, 17, and 22.

Applicant disagrees. Applicant submits that the recitation “the device is provided with a pair of magazines” contained in claims 16, 17, and 22 provides sufficient antecedent basis for the limitation “magazine” in those claims. In addition, in view of the present amendment to claim 15, additional antecedent basis for the limitation “magazine” in claims 16, 17, and 22 can be found in parent claim to claim 15, i.e., claim 1, which recites the limitation “rotatable magazine.” Further, applicant submits that, contrary to the PTO’s statement, the “spool” and “magazine” of the presently claimed device are distinct components. Thus, as clearly shown on Figures 2 and 3 and indicated on page 7, lines 22-23 of the specification, a plurality of spools 2 and carriers 3 are joined in a disc to form magazine 14, where a plurality of dose units 1 are arranged radially around the circumference of magazine 14. Medicament 4 is held within dose unit 1 in the space between spool 2 and the inner walls of spool carrier 3.

In view of the above, the rejection of claims 16, 17, and 22 under 35 U.S.C. § 112 is improper and should be withdrawn.

The rejection of claims 15 and 16 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,778,873 to Braithwaite (“Braithwaite I”) is respectfully traversed in view of the above amendments and the following remarks.

Braithwaite I teaches a metering device for transferring a desired volumetric dose of a flowable substance from a storage chamber containing the flowable substance to a location outside the storage chamber. The metering device is of particular use in a dry powder inhaler. FIGS. 16 and 17 of Braithwaite I show drug-carrying containers for use in the inhaler, where the container has a plurality of receptacles, in each of which receptacles a desired volumetric dose of a substance, e.g., a drug, is held. Container 128 shown in FIG. 17 of Braithwaite I is in the form of a disc which carries around its periphery a series of conduits 129 similar to conduits 122 shown in FIG. 16. When the container is ready for use, each conduit 129 contains a metering device of a similar form to spool 123 shown in FIG. 16, with a desired quantity of drug trapped between the outer flanges of the metering device and the inner walls of the conduit 129. Each of the conduits in the container, thus, contains one dose of the drug, each to be delivered to a user in turn when the container is used in an inhaler.

FIGS. 19A-C show the inhaler of Braithwaite I in various stages of its use. Thus, FIG. 19A show inhaler 140 containing disc-like magazine 145, similar to the container shown in FIG. 17, having a plurality of drug-carrying receptacles around its periphery. Suitable indexing means, including push button 146 and ratchet mechanism 147, engages with upper surface of disc 145. As shown in FIG. 19B, depression of push button 146 (as shown by the arrow) pushes spool 148 *downwards* and almost fully out of a first receptacle, positioned adjacent to inhalation passage 144, into the inhalation passage (FIG. 19B). As spool 148 is pushed into the inhalation passage, it carries with it the measured quantity of drug which it has been used to contain inside magazine 145. The user can then inhale through mouthpiece 142 so as to take up the drug now released into the inhalation passage. The upper flange of the spool remains, however, held by the lower part of the receptacle. When the user then releases push button 146, ratchet mechanism 147 causes disc 145 to rotate by one step so that the next receptacle is brought into register with the inhalation passage 144. The inhaler is, thus, reset and ready for delivery of another dose of drug. The “empty” spool 148, not having been pushed fully out of the first receptacle, continues to move round with the first receptacle, supported by lower guide 150.

Thus, while Braithwaite I discloses a inhaler, i.e., a delivery device, where the spool magazine lies essentially in the same plane as the mouthpiece of the inhaler while the push button actuates the spool in a *perpendicular* plane, nowhere does Braithwaite I teach or suggest a delivery device comprising a metering member, a rotatable magazine having an axis of rotation, a material delivery passage, a material delivery orifice, and at least one actuator member adapted to act upon said metering member so as to move the metering member from a material retaining position to a material dispensing position wherein the actuator member moves in a substantially radial direction relative to the axis of rotation of said magazine and actuates the metering member in said substantially radial direction, characterised in that said metering member is held in the rotatable magazine when acted upon by said actuator member and is ejected in said substantially radial direction into the material delivery passage when moved to the material dispensing position, as set forth in allowed claim 1 of the present application, from which amended claims 15 and 16 depend. In other words, Braithwaite I does not in any way teach or suggest the presently claimed delivery device where a push rod, i.e., the actuator member, lies in essentially the same plane as the delivery orifice of the device and actuates the spool in a direction which is *coaxial* with the

delivery orifice of the device. Thus, in the presently claimed invention, a plurality of spools are arranged radially in a magazine such that the longitudinal axis of the spools lie in the same plane as the magazine and the spools may be expressed radially from the magazine.

Since Braithwaite I fails to teach or suggest the claimed delivery device, the anticipatory rejection based on this reference is improper and should be withdrawn.

The rejection of claim 17 under 35 U.S.C. § 103(a) for obviousness over Braithwaite I as applied to claim 15 is respectfully traversed.

As noted above, Braithwaite I fails to teach or suggest the present invention of claim 1, from which amended claim 15, as well as claim 17, depends. In particular, Braithwaite I does not teach or suggest a delivery device comprising a metering member, a rotatable magazine having an axis of rotation, a material delivery passage, a material delivery orifice, and at least one actuator member adapted to act upon said metering member so as to move the metering member from a material retaining position to a material dispensing position wherein the actuator member moves in a substantially radial direction relative to the axis of rotation of said magazine and actuates the metering member in said substantially radial direction, characterised in that said metering member is held in the rotatable magazine when acted upon by said actuator member and is ejected in said substantially radial direction into the material delivery passage when moved to the material dispensing position, as required by claim 1 of the present application. Thus, Braithwaite I could not have rendered obvious the subject matter of claim 17.

Since Braithwaite I fails to teach or suggest the claimed delivery device, the rejection under 35 U.S.C. § 103(a) based on this reference is improper and should be withdrawn.

The rejection of claim 22 under 35 U.S.C. § 103(a) for obviousness over Braithwaite I in view of U.S. Patent No. 6,698,425 to Widerström ("Widerström") as applied to claim 17 is respectfully traversed.

Widerström is cited for teaching the use of fluticasone and salmeterol in a powder inhaler as suitable medicaments. However, even if this is true, Widerström does not overcome the above-noted deficiencies of Braithwaite I.

Thus, the rejection of claim 22 (which is dependent from claim 17, which is dependent from claim 15, which is dependent from claim 1) for obviousness over Braithwaite I in view of Widerström is improper and should be withdrawn.

The rejection of claim 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4 of U.S. Patent No. 5,924,417 to Braithwaite ("Braithwaite II") is respectfully traversed in view of the above amendments and the following remarks.

Claims 1, 2, and 4 of Braithwaite II are drawn to an inhaler for delivering a substance in a finely divided form, where the inhaler comprises: air intake means by which air is able to be drawn into the inhaler from the atmosphere; an inhalation passage communicating with the air intake means, through which the inhalation passage air is able to be drawn using the air intake means; a receptacle having inner walls in combination with a metering device located within the receptacle having a first end element and a second end element sealing against the inner walls of the receptacle for defining an intermediate dosing space loaded with a desired volumetric dose of a substance, the metering device and the receptacle being dimensioned so that the metering device has a tendency to remain in the receptacle unless actively urged out of the receptacle; indexing means operable for moving the receptacle into a position in, or adjacent to, the inhalation passage; and means for urging the metering device, at least partially, out of the receptacle for releasing the dose of the substance contained in the receptacle into the inhalation passage when the receptacle occupies its position in, or adjacent to, the inhalation passage.

Thus, claims 1, 2, and 4 of Braithwaite II are not directed to "[a] delivery device comprising a metering member adapted to dispense a measured amount of material, a rotatable magazine having an axis of rotation, a material delivery passage, a material delivery orifice, and at least one actuator member adapted to act upon said metering member so as to move the metering member from a material retaining position to a material dispensing position wherein the actuator member moves in a substantially radial direction relative to the axis of rotation of said magazine and actuates the metering member in said substantially radial direction, characterised in that said metering member is held in the rotatable magazine when acted upon by said actuator member and is ejected in said substantially radial direction into the material delivery passage when moved to the material dispensing position (emphasis added)" as set forth in allowed claim 1 of the present application, from which amended claim 15 depends.

Since claims 1, 2, and 4 of Braithwaite II fail to teach or suggest the claimed delivery device, applicant submits that the obviousness-type double patenting rejection of claim 15 is improper and should be withdrawn.

The rejection of claim 15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 16, 18, and 19 of U.S. Patent No. 6,845,772 to Braithwaite ("Braithwaite III") is respectfully traversed in view of the above amendments and the following remarks.

Claims 1, 12, 16, 18, and 19 of Braithwaite III are drawn to a delivery device which comprises a plurality of reservoirs, two delivery passages for the delivery of material and a metering member, wherein the metering member is a frusto conical member provided with a plurality of measuring cups adapted to transfer one or more measured doses of material from one or more of the reservoirs to the delivery passages.

Thus, claims 1, 12, 16, 18, and 19 of Braithwaite III are not directed to "[a] delivery device comprising a metering member adapted to dispense a measured amount of material, a rotatable magazine having an axis of rotation, a material delivery passage, a material delivery orifice, and at least one actuator member adapted to act upon said metering member so as to move the metering member from a material retaining position to a material dispensing position wherein the actuator member moves in a substantially radial direction relative to the axis of rotation of said magazine and actuates the metering member in said substantially radial direction, characterised in that said metering member is held in the rotatable magazine when acted upon by said actuator member and is ejected in said substantially radial direction into the material delivery passage when moved to the material dispensing position (emphasis added)" as set forth in allowed claim 1 of the present application, from which amended claim 15 depends.

Since claims 1, 12, 16, 18, and 19 of Braithwaite III fail to teach or suggest the claimed delivery device, applicant submits that the obviousness-type double patenting rejection of claim 15 is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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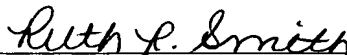
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